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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-03-02

October 2, 2002

Julie Ann Russell, President
Pelican Point Seafood Inc.
933 Dodecanese Blvd
Tarpon Springs, Florida 34689

Dear Ms. Russell:

We inspected your firm, located at 933 Dodecanese Blvd, Tarpon Springs, Florida 34689 on July 9-10, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your cooked stone crab claws are adulterated, in that the crab claws have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

- (1) You must, at a minimum, conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for cooked stone crab claws does not list the following critical control points for controlling the food safety hazard of pathogen growth and toxin formation:

- a. Your firm's HACCP plan does not list a cooling critical control point. A cooling critical control point is necessary to insure that the cooked ready-to-eat product is chilled below 70° F within an acceptable period of time following the cooking process. The FDA recommends that the temperature of cooked ready-to-eat products be reduced to 70° F and below within 2 hours. The FDA also recommends that ready-to-eat products be further cooled to 50° F or below within 4 hours. If the cooked ready-to-eat product is held at temperatures above 70° F for more than 2 hours, the FDA recommends that it be cooled to 50° F or lower within 2 hours.
- b. Your firm does not list a refrigerated storage critical control point. A finished product storage critical control point is necessary to control pathogen growth in cooked ready-to-eat products. The FDA recommends that cooked ready-to-eat products such as cooked stone crab claws be held in refrigerated storage at a temperature not to exceed 40° F to control pathogen growth.

(2) You must, at a minimum, implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Cooking critical control point to control bacterial pathogens listed in your HACCP plan for stone crab claws.

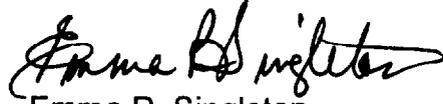
We acknowledge your statement promising corrective action during our inspection. However, we have not received any written response addressing these corrections. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, monitoring records and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal stroke at the end.

Emma R. Singleton
Director, Florida District